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14
15 **UNITED STATES DISTRICT COURT**
16 **NORTHERN DISTRICT OF CALIFORNIA**
17 **SAN FRANCISCO DIVISION**

18 AIDS HEALTHCARE FOUNDATION,
INC.,

19 Plaintiff,

20 v.

21 GILEAD SCIENCES, INC.; JAPAN
22 TOBACCO, INC.; JAPAN TOBACCO
23 INTERNATIONAL U.S.A., INC.; AND
EMORY UNIVERSITY

24 Defendants.

) Case No. 3:16-cv-00443-WHA

) **JAPAN TOBACCO INTERNATIONAL**
) **U.S.A., INC.'S NOTICE OF MOTION**
) **AND MOTION TO DISMISS**
) **COMPLAINT UNDER RULE 12(b)(6);**
) **MEMORANDUM OF POINTS AND**
) **AUTHORITIES**

) Hearing Date: April 28, 2016

) Hearing Time: 8:00 a.m.

) Before: Hon. William H. Alsup
Courtroom 8, 19th Floor

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TO ALL PARTIES AND THEIR COUNSEL OF RECORD:

PLEASE TAKE NOTICE THAT, on April 28, 2016, at 8:00 a.m., or as soon thereafter as counsel may be heard, defendant Japan Tobacco International U.S.A., Inc. ("JTI USA") will and hereby does move to dismiss the complaint ("Complaint") of plaintiff AIDS Healthcare Foundation, Inc. ("Plaintiff") filed on January 26, 2016.

JTI USA brings this motion pursuant to Rule 12(b)(6) of the Federal Rules of Civil Procedure. By this motion, JTI USA asks this Court to dismiss Plaintiff's Complaint, and all purported causes of action therein against JTI USA, for failure to state a claim upon which relief can be granted. Because it is evident that amendment of the Complaint would be futile, JTI USA seeks dismissal of the Complaint against it with prejudice.

This motion is and will be based on this notice of motion and motion, the following memorandum of points and authorities, the accompanying Request for Judicial Notice and exhibits thereto, the Declaration of Jerome W. Hoffman in Support of Japan Tobacco International U.S.A., Inc.'s Request for Judicial Notice, the accompanying [Proposed] Order, the Complaint and other pleadings on file in this matter including the reply memorandum JTI USA expects to file, and such other matters and argument as the Court may properly consider.

Dated: March 21, 2016

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 JEROME W. HOFFMAN
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By: /s/ Jerome W. Hoffman
 Jerome W. Hoffman

Attorneys for Defendant JAPAN TOBACCO
 INTERNATIONAL U.S.A., INC.

MEMORANDUM OF POINTS AND AUTHORITIES

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1 **I. LEGAL STANDARD**

2 On a motion to dismiss under Federal Rule of Civil Procedure 12(b)(6), all allegations of
 3 material facts are assumed to be true and construed in the light most favorable to the non-moving
 4 party. *Cousins v. Lockyer*, 568 F.3d 1063, 1067 (9th Cir. 2009). However, dismissal under Rule
 5 12(b)(6) can be based on “the lack of a cognizable legal theory” or “the absence of sufficient facts
 6 alleged under a cognizable legal theory.” *Balistreri v. Pacifica Police Dept.*, 901 F.2d 696, 699
 7 (9th Cir. 1990). The principle that a court accepts as true all of the allegations in a complaint does
 8 not apply to legal conclusions or conclusory factual allegations. *Ashcroft v. Iqbal*, 566 U.S. 662,
 9 678 (2009) (“Threadbare recitals of the elements of a cause of action, supported by mere conclusory
 10 statements, do not suffice.”). Further, as stated in *Iqbal*, a claim has facial plausibility only when
 11 the Plaintiff “pleads factual content that allows the Court to draw the reasonable inference that the
 12 Defendant is liable for the misconduct alleged.” *Id.* To show that the Plaintiff is entitled to relief,
 13 the Complaint must “permit the Court to infer more than the mere possibility of misconduct.” *Id.*
 14 Here, the Complaint fails to meet that standard and should be dismissed. Because it is evident that
 15 the deficiencies in the Complaint would not be curable by amendment, the dismissal should be with
 16 prejudice.

17 Plaintiff lacks standing to pursue against Japan Tobacco International U.S.A., Inc.
 18 (hereinafter, “JTI USA”) a claim for declaratory judgment as to any of the patents identified in
 19 Count I of the Complaint. Declaratory judgment jurisdiction exists only where there is a
 20 controversy of sufficient “immediacy and reality” to create a justiciable controversy. *Prasco LLC*
 21 *v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338 (Fed. Cir. 2008); *see also MedImmune v. Genentech*,
 22 549 U.S. 118, 127 (2007) (a dispute giving rise to declaratory judgment jurisdiction in the patent
 23 context must be “definite and concrete, touching the legal relations of parties having adverse legal
 24 interests,” such that the dispute is “real and substantial” and “admi[ts] of specific relief through a
 25 decree of a conclusive character, as distinguished from an opinion advising what the law would be
 26 upon a hypothetical state of facts.”). Here, Plaintiff has failed to allege any concrete, actual or
 27 imminent harm to it that is traceable to JTI USA’s conduct concerning any of the patents identified

1 in Count I of the complaint. Nor, as explained below, can Plaintiff possibly make any such
 2 allegation. Accordingly, Plaintiff lacks standing to seek declaratory judgment against JTI USA on
 3 the validity of any of the patents identified in this lawsuit.

4 **II. PLAINTIFF FAILS TO PLEAD FACTS TO CONNECT JTI USA TO THE**
 5 **EXCLUSIVE LICENSING AGREEMENT**

6 Other than to describe defendant JTI USA in paragraph 38, the Complaint contains no
 7 specific factual allegations as to JTI USA. In paragraph 39 of the Complaint, Plaintiff amalgamates
 8 Japan Tobacco Inc. and Japan Tobacco International U.S.A., Inc. into a single entity that Plaintiff
 9 refers to misleadingly as “Japan Tobacco.” This impermissibly ignores the fact that Japan Tobacco
 10 Inc. and JTI USA are two separate corporate entities. The portion of the Gilead Sciences 10-K
 11 filing from 2014 quoted in paragraph 39 refers to “Japan Tobacco” and not to JTI USA. However,
 12 the full 10-K filing by Gilead reveals that the entity with whom it entered into the exclusive
 13 licensing agreement was Japan Tobacco, Inc. not JTI USA).¹ Furthermore, attached to JTI USA’s
 14 accompanying Request for Judicial Notice (“RJN”) is a public copy of the exclusive licensing
 15 agreement between Japan Tobacco Inc. and Gilead Sciences, Inc. that was made public as part of an
 16 SEC filing.² It is indisputable that JTI USA is not a party to that exclusive licensing agreement.

17 In addition, it is indisputable that Plaintiff has not alleged that JTI USA is the owner of any
 18 of the patents identified in Count I of the Complaint including U.S. Patent No. 8,633,219.³ In sum,

19
 20 ¹ See RJN Exhibit B. Gilead’s full 2014 10-K Filing makes clear that Gilead entered into the
 21 exclusive licensing agreement only with Japan Tobacco Inc. and *not* JTI USA. “In 2005, Japan
 22 Tobacco Inc. (Japan Tobacco) granted us exclusive rights to develop and commercialize
 elvitegravir, a novel HIV integrase inhibitor, in all countries of the world, excluding Japan, where
 Japan Tobacco retained such rights.” RJN Ex. B at p. 97.

23 ² See JTI USA’s Request for Judicial Notice (“RJN”), Exhibit A. The public version of
 24 Gilead’s 2005 Licensing Agreement states that it is “by and between Japan Tobacco Inc., a
 25 Japanese corporation having its principal place of business at JT Building, 2-1 Toranomom, 2-
 chome, Minato-ku, Tokyo 105-8422, Japan (“JT”), and Gilead Sciences, Inc.” RJN Ex. A at page 1

26 ³ See RJN Exhibit C at p. 1. The official patent, obtained from the United States Patent and
 27 Trademark Office, clearly identifies Japan Tobacco Inc.—and not JTI USA—as the owner of U.S.
 Patent No. 8,633,219 (the “219 Patent”). Nowhere is JTI USA identified as the assignee of the

the Complaint fails to allege facts that would support a contention that JTI USA actually has anything to do with the allegations in the Complaint, that JTI USA ever had any rights with respect to the '219 Patent, or that JTI USA has entered into any agreements with anyone with respect to the '219 Patent. As the judicially-noticeable documents attached as Exhibits A, B and C to JTI USA's RJN establish without question, JTI USA has no involvement with any of the exclusive licenses to Gilead that are the subject matter of Plaintiff's Complaint. These reasons are, in and of themselves, sufficient to require dismissal of JTI USA from the Complaint.

III. PLAINTIFF FAILS TO PLEAD FACTS TO SUPPORT A PLAUSIBLE LEGAL THEORY AGAINST JTI USA

A. JTI USA Is Not Separately Identified in Counts I or III⁴

Defendant JTI USA is not specifically included in Counts I or III of the Complaint.⁵ Instead, the Complaint makes allegations against "Japan Tobacco," a term that Plaintiff defines to include both Japan Tobacco Inc. and JTI USA. Paragraph 47 of the Complaint alleges that "each of the Defendants has purposely conducted its patent enforcement activities in this district and towards residents of this District." As noted above, however, JTI USA could not possibly have enforced any rights with respect to the '219 Patent because it is not alleged (and cannot plausibly be alleged) that it has any.

⁴ '219 Patent. The remaining patents set forth in the Complaint are alleged to be owned by Gilead. Hence none of the patents are assigned to or owned by JTI USA.

⁴ Count II of the Complaint, for alleged "illegal monopolization" under section 2 of the Sherman Act (15 U.S.C. § 2), is directed only against Gilead.

⁵ Paragraph 124 of the Complaint states, "Defendant Japan Tobacco and Defendant Gilead entered into an exclusive license agreement for patents relating to elvitegravir." It is unclear whether the reference to "Japan Tobacco" in Paragraph 124 is intended to apply to both Japan Tobacco Inc. and Japan Tobacco International U.S.A., Inc. They are in fact identified and named as separate Defendants. The language in Paragraph 124 refers only to "*Defendant* Japan Tobacco" not to both Defendants Japan Tobacco Inc. and JTI USA. (emphasis supplied).

B. Allegations Made on “Information and Belief” Cannot Survive a Motion To Dismiss

The allegation in Count I that Gilead is the assignee of the ‘219 Patent and the allegations against Defendant JTI USA in Count III are all made “on information and belief.” These allegations are not sufficient to defeat a motion to dismiss. “In the post-*Twombly* and *Iqbal* era, pleading on information and belief, without more, is insufficient to survive a motion to dismiss for failure to state a claim.” *Solis v. City of Fresno*, No. 1:11-cv-00053-AWI-GSA, 2012 WL 868681 at *8 (E.D. Cal. Mar. 13, 2012). “The facts alleged must be sufficient to nudge the claims ‘across the line from conceivable to plausible’” *Id.* (citing *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 547 (2007)); *see also Vivendi SA v. T-Mobile USA Inc.*, 586 F.3d 689, 694 (9th Cir. 2009) (finding insufficient allegations made “upon information and belief”); *Klohs v. Wells Fargo Bank, N.A.*, 901 F. Supp. 2d 1253, 1260 n. 2 (D. Haw. 2012). “[A]lthough allegations ‘upon information and belief’ may state a claim after *Iqbal* and *Twombly*, a claim must still be based on factual content that makes liability plausible, and not be ‘formulaic recitations of the elements of a cause of action.’” *Tesi v. Recon Trust, N.A.*, 2013 WL 2635613, *4 (D. Ariz. June 12, 2013); *Dean v. Allred*, 2014 WL 231992, at *4 (D. Ariz. Jan. 22, 2014); *Joshua David Mellberg LLC v. Will*, 96 F. Supp.3d 953, 989 (D. Ariz. 2015); *Talbot v. Reliance Standard Life Ins. Co.*, 2015 WL 4134548 at *9 (D. Ariz. June 18, 2015); *Simonyan v. Ally Financial Inc.* 2013 WL 45453 at *2 (C.D. Cal. Jan. 3, 2013).

Here the allegations of Counts I and III contain no additional plausible facts to support the “upon information and belief” allegations. Paragraphs 109, 124, 125 and 127 make allegations against “Japan Tobacco” that are clearly false as to JTI USA.⁶

As shown above, JTI USA is not identified as the owner of the ‘219 Patent and was not a

⁶ Furthermore, the Complaint is internally inconsistent. The Complaint alleges at paragraph 109 that, “Upon information and belief, Gilead is the current assignee of the ‘791, ‘788, ‘065, ‘374 and ‘219 Patents (collectively, the ‘TAF Patents’).” But this allegation is directly contradicted by Paragraph 40 that states, “Japan Tobacco” owns the ‘219 Patent, which it has licensed to Gilead.

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party to the exclusive licensing agreement with Gilead. The remaining allegations in Count III are against “Japan Tobacco,” not specifically against JTI USA. Count III contains only formulaic recitations of conclusory allegations. For example, Paragraph 127 alleges that “Japan Tobacco entered into an agreement and conspiracy with Gilead to license patents covering ... elvitegravir with the knowledge and intent that Gilead would use those patents to erect barriers to entry that would create and maintain unjustified monopoly profits on the sale of TAF.” There are no allegations of facts to explain the when, where or how of the alleged conspiracy. *Kendall v. Visa USA, Inc.*, 518 F.3d 1042, 1046-47 (9th Cir. 2008); *Pharmarx Pharm., Inc. v. GE Healthcare, Inc.*, 596 Fed.Appx. 580, 581 (9th Cir. 2015); *Credit Bureau Servs, Inc. v. Experian Info. Solutions, Inc.*, No. SACV 12–2146 JGB, 2013 WL 3337676 at *8 (C.D. Cal. June 28, 2013); *Song Fi v. Google, Inc.*, Case No. 14-5080 SC, 2015 WL 6552377 at *3 (N.D. Cal. October 29, 2015); *In re Animation Workers Antitrust Litig.*, 87 F.Supp.3d 1195, 1217 (N.D. Cal. 2015); *Realnetworks, Inc. v. DVD Copy Control Ass’n, Inc.*, Nos. C 08–4548 MHP, 2010 WL 145098 at *7 (N.D. Ca. Jan. 8, 2010).

Moreover, these allegations in Count III as against JTI USA are implausible. First, as noted above, JTI USA was not a party to the exclusive licensing agreement with Gilead identified in the Complaint. Second, the allegations in the Complaint at Paragraph 39 state that the exclusive licensing agreement between Gilead and “Japan Tobacco” was entered into in 2005. However, as alleged in Paragraph 9 of the Complaint, Gilead did not introduce a product containing TAF (Genvoya®) until November 2015. Thus, the allegations of conspiracy in Count III amount to a theory that in 2005, JTI USA entered into an agreement with Gilead whereby JTI USA “knew or should have known” that by entering into an exclusive licensing agreement with Gilead, Gilead would “use those patents to erect barriers to entry that would create and maintain unjustified monopoly profits on the sale of TAF.” In other words, Plaintiff alleges that JTI USA knew or should have known ten years in advance (when it allegedly entered into an exclusive licensing agreement with Gilead) that Gilead would be able to use the exclusive license to “erect barriers to entry that would create and maintain unjustified monopoly profits on the sale of TAF” a product for which Gilead had discontinued development and which might never be successful. Absent detailed

1 facts explaining the who, when and how of such a conspiracy, these claims are facially implausible
2 and cannot survive a motion to dismiss under the *Twombly/Iqbal* standard.

3 **C. A Patent Holder Cannot Conspire With an Exclusive Licensee**

4 Plaintiff fails to state a cause of action against JTI USA for conspiracy under Section 1 of
5 the Sherman Act because a patent holder is legally incapable of conspiring with an exclusive
6 licensee to violate the antitrust laws. *Levi Case Co., Inc. v. ATS Prods, Inc.*, 788 F. Supp. 428, 431-
7 432 (N.D. Cal. 1992) (“a grant of an exclusive license excludes even the patent holder himself from
8 exercising the rights conveyed by the license. The exclusive license, by itself, does not constitute a
9 legal restraint under the antitrust laws.” (omitting internal citations)). In that case, the Court noted
10 that the patent holder, Shea, had conveyed, by exclusive license to Sterling Imperial, rights to its
11 patent and that Shea, by virtue of the exclusive license, could not compete in the manufacture of the
12 duct work covered by the patent. Sterling later granted a sub-license to ATS. Based on these facts,
13 the court found that no agreement between ATS and Shea involving exploitation of the patent in
14 which they both held an interest could be considered to deprive the marketplace of any
15 “independent sources of economic power previously pursuing separate interest.” Thus, the court
16 held that ATS and Shea could not “conspire” in violation of the antitrust laws. *Id.* at 432.

17 Here the allegation is that JTI USA, by virtue of its alleged exclusive licensing agreement
18 with Gilead, conspired with Gilead to violate the antitrust laws by agreeing to an exclusive patent
19 license with Gilead. Leaving aside the fact that JTI USA never entered into a licensing agreement
20 with Gilead, under the authority cited above, such a conspiracy is impossible as a matter of law.
21 Plaintiff’s conspiracy allegations against JTI USA in Count III should be dismissed.

22 **IV. PLAINTIFF FAILED TO ALLEGE A RELEVANT MARKET AS REQUIRED**
23 **UNDER THE RULE OF REASON**

24 The allegations of the Complaint make it clear that the supposed relationship between
25 Gilead and JTI USA is vertical, not horizontal. According to Paragraph 39, JTI USA has allegedly
26 licensed whatever rights to the patents at issue it had (none) to Gilead. Therefore JTI USA can no
27 longer compete directly against Gilead in the sale of any products containing or based on any of the
28

1 licensed patents. The relationship between a patentee and its licensee is vertical, not horizontal. *See*
 2 *Mannington Mills, Inc. v. Congoleum Indus., Inc.*, 610 F.2d 1059, 1070 (3d Cir. 1979) (recognizing
 3 that patentee and licensee are in vertical relationship); *Int'l Wood Processors v. Power Dry, Inc.*,
 4 792 F.2d 416, 429 (4th Cir. 1986) (same); *Brantley v. NBC Universal, Inc.* 675 F.3d 1192, 1198
 5 (9th Cir. 2012) (recognizing that vertical agreements are “agreements between firms operating at
 6 different levels of a given product market,” such as agreements between a supplier and a
 7 distributor).

8 Thus, any agreement between a patentee and its licensee is not *per se* unlawful and must be
 9 judged under the rule of reason. *See Leegin Creative Leather Prods. v. PSKS, Inc.*, 551 U.S. 877,
 10 882 (2007) (abandoning the rule of “per se illegality” and holding that “vertical price restraints are
 11 to be judged by the rule of reason”); *Transource Int'l, Inc. v. Trinity Indus., Inc.*, 725 F.2d 274,
 12 279-80 (5th Cir. 1984) (“Vertical restraints ... are those imposed further up the chain of
 13 distribution, and are tested by the ‘rule of reason.’”); *Anderson News, L.L.C. v. American Media,*
 14 *Inc.*, 680 F.3d 162, 183 (2d Cir. 2012)(“Vertical restraints ... are generally judged under the rule of
 15 reason, which requires a weighing of the relevant circumstances of a case to decide whether a
 16 restrictive practice constitutes an unreasonable restraint on competition.”). Because the rule of
 17 reason applies, Plaintiffs must properly allege both a relevant product market and relevant
 18 geographic market. *See Orchard Supply Hardware LLC v. Home Depot USA, Inc.*, 967 F. Supp. 2d
 19 1347, 1357 (N.D. Cal. 2013) (“To establish a rule of reason violation a plaintiff must ... allege
 20 sufficient facts to support its claim that the restraint in question harmed competition within a
 21 relevant geographic and product market.”); *Big Bear Lodging Ass'n v. Snow Summit, Inc.*, 182 F.3d
 22 1096, 1104-05 (9th Cir. 1999) (“Plaintiffs must identify the relevant geographic and product
 23 markets in which Plaintiffs and Defendants compete and allege facts demonstrating that
 24 Defendants’ conduct has an anticompetitive effect on those markets.”). Count III of the Complaint
 25
 26
 27
 28

contains no specific definitions or allegations related to any relevant product market or relevant geographic market.⁷ In the absence of such allegations, Count III should be dismissed.

V. PLAINTIFF LACKS STANDING TO SUE FOR ANTITRUST DAMAGES

Pursuant to the United States Supreme Court's ruling in *Illinois Brick Co. v. Illinois*, 431 U.S. 720 (1977), Plaintiff does not have standing to sue for money damages under Section 1 of the Sherman Act. In *Illinois Brick*, the Court ruled that persons (so-called "indirect purchasers") who do not purchase directly from one of the members of an alleged conspiracy, but instead purchase from independent wholesalers or distributors, may not sue for damages under Section 4 of the Clayton Act. *Id.* at 737-738. The Court found that tracing any alleged overcharge through multiple distributors at various levels in the chain of distribution would make trials cumbersome. *Id.* at 740-41. It also reasoned that allowing indirect purchasers to sue would diminish the likelihood of suits being brought and thereby reduce deterrence; and would raise the possibility of duplicate recovery. *Id.* at 730-31.

Here, Plaintiff does not allege that it purchased Genvoya[®] directly from any of the alleged co-conspirators. In fact, quite to the contrary, Plaintiff alleges at Paragraph 7 that Gilead does not sell TAF on a standalone basis to anyone. Plaintiff further admits that it does not purchase Genvoya[®] (the brand name of the only approved drug that contains TAF) from any of the alleged co-conspirators. Plaintiff states at Paragraph 18 that "AHF placed its first order for Genvoya[®] on November 9, 2015. AHF primarily orders Genvoya from Cardinal Health. Cardinal is one of twenty-five Gilead authorized distributors (AD) of record." Nowhere does Plaintiff allege that it has

⁷ Count III does not incorporate by reference any prior relevant market definitions. But in any event, courts have repeatedly rejected at the motion to dismiss stage a relevant product market definition that includes only a single product as Plaintiff postulates here. *See, e.g., Satnam Distributors LLC v. Commonwealth-Altadis, Inc.*, --- F.Supp.3d ----, Case No. 14-6660, 2015 WL 5971583 at *10 (E.D. Pa. Oct. 14, 2015); *Carell v. Shubert Org.*, 104 F.Supp.2d 236, 264-65 (S.D.N.Y.2000); *Deep S. Pepsi-Cola Bottling Co. v. Pepsico, Inc.*, 1989 WL 48400, at *8 n. 1 (S.D.N.Y. May 2, 1989); *Theatre Party Assocs., Inc. v. Shubert Org., Inc.*, 695 F. Supp. 150, 154 (S.D.N.Y. 1988); *Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1064 (9th Cir. 2001).

1 purchased Genvoya[®] directly from any of the alleged co-conspirators.⁸ Thus, because Plaintiff does
 2 not purchase Genvoya[®] directly from Gilead or from any of the other alleged co-conspirators, it
 3 does not have standing to sue those alleged co-conspirators for damages based on the *Illinois Brick*
 4 doctrine. As such Plaintiff's claims for damages should be dismissed.

5 VI. PLAINTIFF LACKS STANDING TO SUE TO INVALIDATE THE '219 PATENT

6 Plaintiff lacks standing to pursue against JTI USA a claim for declaratory judgment as to
 7 Japan Tobacco Inc.'s '219 Patent, as pled in Count I of the Complaint. Declaratory judgment
 8 jurisdiction exists only where there is a controversy of sufficient "immediacy and reality" to create
 9 a justiciable controversy, *i.e.*, (1) an injury-in-fact, *i.e.*, a harm that is concrete and actual or
 10 imminent, not conjectural or hypothetical, (2) that is fairly traceable to the defendant's conduct, and
 11 (3) redressable by a favorable decision. *Prasco LLC v. Medicis Pharm. Corp.*, 537 F.3d 1329, 1338
 12 (Fed. Cir. 2008); *see also MedImmune v. Genentech*, 549 U.S. 118, 127 (2007) (a dispute giving
 13 rise to declaratory judgment jurisdiction in the patent context must be "definite and concrete,
 14 touching the legal relations of parties having adverse legal interests," such that the dispute is "real
 15 and substantial" and "admi[ts] of specific relief through a decree of a conclusive character, *as*
 16 *distinguished from an opinion advising what the law would be upon a hypothetical state of*
 17 *facts.*") (emphasis added).

18 Here, Plaintiff has failed to allege any concrete, and actual or imminent harm to it that is
 19 traceable to JTI USA's conduct concerning the '219 Patent.⁹ Nor can Plaintiff possibly make that

20 ⁸ Plaintiff alleges at Paragraph 19 that in 2015 it purchased "millions of dollars of antiviral
 21 pharmaceutical drugs from Gilead," but it does not allege that it purchased Genvoya directly from
 Gilead.

22 ⁹ Plaintiff's allegation that it suffers a "reasonable apprehension" that it would face a patent
 23 infringement suit from *Gilead* were Plaintiff to sell, import, develop, distribute, and/or test an
 24 unlicensed or standalone drug containing TAF (Compl., ¶¶ 21-26) is implausible. First, Plaintiff's
 25 entire basis for alleging antitrust injury is due precisely to a *lack* of any unlicensed or standalone
 26 drug containing TAF. *See, e.g.*, Compl., ¶¶ 7, 8, 21. Second, Plaintiff fails to plead any facts to
 suggest that Gilead has ever sued Plaintiff for the infringement of any patent, let alone that Gilead
 intends to sue Plaintiff for the infringement of the '219, '791, '788, '065, '374 patents specifically
 mentioned in the Complaint. To the contrary, Plaintiff's Complaint reveals that Plaintiff repeatedly
 has attempted to provoke Gilead on a variety of unrelated matters, without success. [Compl., ¶ 22.]

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allegation. The ‘219 Patent (as to which there is no allegation that JTI USA has any rights whatsoever) claims methods and compositions including two, three-drug combinations (elvitegravir, TAF and emtricitabine, and elvitegravir, TDF and emtricitabine). By Plaintiff’s own admission, Plaintiff purchased from Gilead’s authorized distributors the Genvoya® product that embodies that elvitegravir-TAF-emtricitabine combination. Compl. ¶¶ 9, 14, 18, 19, 106. Under the doctrine of patent exhaustion, the lawful sale and purchase of an article that embodies the substantial features of the patent in question exhausts the patentee’s—here, Japan Tobacco Inc.’s—rights and bars the patentee from suing the purchaser for patent infringement. *See, e.g., LifeScan Scotland Ltd. v. Shasta Techs., LLC*, 734 F.3d 1361, 1367 (Fed. Cir. 2013); *see also Quanta Computer v. LG Elec.*, 533 U.S. 617, 638 (2008) (“[a]n authorized sale of an article that substantially embodies a patent exhausts the patent holder’s rights and prevents the patent holder from invoking patent law to control postsale use of the article.”). Plaintiff does not allege that its purchases of Genvoya® from Gilead’s authorized distributors were unauthorized. And Plaintiff does not allege that there exist any elvitegravir-TAF-emtricitabine combination drug products besides Genvoya® that are within the scope of the ‘219 Patent as would be required to establish a claim of infringement. (Indeed, Plaintiff’s entire basis for alleging antitrust injury here is due precisely to the *lack* of a standalone TAF product. *See, e.g., Compl.*, ¶¶ 7, 8, 21.) Plaintiff thus faces no harm—whether concrete or conjectural—from the ‘219 Patent and likewise no injury would be redressed by a declaration of invalidity of the ‘219 Patent. For at least these reasons, Plaintiff lacks standing to seek declaratory judgment on the validity of the ‘219 Patent.

VII. CONCLUSION

Plaintiff has wholly failed to state any claim against JTI USA. The allegations in the Complaint fail to specify JTI USA’s involvement with Gilead or with the patents in question, but rather are only vague and conclusory “information and belief” allegations against “Japan Tobacco.” These allegations do not satisfy the *Twombly/Iqbal* standard. The facts as established by examination of the actual documents to which Plaintiff refers in its Complaint are that JTI USA is not a party to the Exclusive License Agreement with Gilead and has not been alleged to have any

1 interest in any of the patents mentioned in the Complaint. For these reasons alone, JTI USA should
2 be dismissed with prejudice. Additionally, the Complaint alleges an antitrust conspiracy that: (1) is
3 not plausible; (2) cannot exist as a matter of law; (3) fails to specify proper relevant product and
4 geographic markets; and (4) impermissibly seeks damages for indirect purchases. All of these
5 provide independent grounds to dismiss the Complaint with prejudice as to JTI USA.

6
7 Dated: March 21, 2016

HOLLAND & KNIGHT LLP

8
9 By: /s/ Jerome W. Hoffman

Neal N. Beaton

Jerome W. Hoffman

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11 Attorneys for Defendant Japan Tobacco International
12 U.S.A., Inc.

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